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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THERAVANCE BIOPHARMA R&D IP, LLC, THERAVANCE BIOPHARMA US, INC., THERAVANCE BIOPHARMA IRELAND LIMITED, MYLAN IRELAND LIMITED, and MYLAN SPECIALTY L.P.,	
Plaintiffs,	C.A. No. _____
v.	***Document Filed Electronically***

EUGIA PHARMA SPECIALITIES LTD., EUGIA US LLC, AUROBINDO PHARMA USA, INC., AUROBINDO PHARMA LIMITED, MANKIND PHARMA LTD., LIFESTAR PHARMA LLC, TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., ACCORD HEALTHCARE, INC., ACCORD HEALTHCARE, LTD., INTAS PHARMACEUTICALS LTD., LUPIN INC., LUPIN LTD., LUPIN PHARMACEUTICALS, INC., ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED, CIPLA LIMITED, and CIPLA USA, INC.,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Theravance Biopharma R&D IP, LLC, Theravance Biopharma US, Inc., Theravance Biopharma Ireland Limited, Mylan Ireland Limited, and Mylan Specialty L.P. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants Mankind Pharma Ltd. ("Mankind Pharma"), Lifestar Pharma LLC ("Lifestar") (collectively, "Mankind"); Teva Pharmaceuticals, Inc. ("Teva Pharmaceuticals"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Pharmaceutical Industries Ltd. ("Teva Industries") (collectively, "Teva"); Accord Healthcare, Inc. ("Accord Inc."), Accord Healthcare, Ltd. ("Accord Ltd."), Intas Pharmaceuticals Ltd. ("Intas") (collectively, "Accord"); Eugia Pharma Specialities Ltd. ("Eugia Pharma"), Eugia US LLC ("Eugia US"), Aurobindo Pharma USA, Inc. ("Aurobindo USA"), Aurobindo Pharma Limited ("Aurobindo Ltd.") (collectively, "Eugia"); Lupin Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively, "Lupin"); Orbicular Pharmaceutical Technologies Private Limited ("Orbicular"); and Cipla Limited ("Cipla Ltd."), and

Cipla USA, Inc. ("Cipla USA") (collectively, "Cipla") (all named defendants, collectively, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 11,691,948 (the "'948 patent") arising under the Patent Laws of the United States, Title 35, United States Code, Section 1 *et seq*. This action relates to Abbreviated New Drug Application ("ANDA") No. 218089, filed by Mankind; ANDA No. 217015, filed by Teva; ANDA No. 218100, filed by Accord; ANDA No. 218128, filed by Eugia; ANDA No. 218088, filed by Lupin; ANDA No. 217868, filed by Orbicular; and ANDA No. 217958, filed by Cipla, with the United States Food and Drug Administration ("FDA") for approval to market generic versions of YUPELRI® (revefenacin) inhalation solution, for oral inhalation, prior to the expiration of patents listed in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") for YUPELRI®, including the '948 patent.

THE PARTIES

Plaintiffs

2. Plaintiff Theravance Biopharma R&D IP, LLC is a Delaware limited liability company having a principal place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080.

3. Plaintiff Theravance Biopharma US, Inc. is a Delaware corporation having a principal place of business at 901 Gateway Boulevard, South San Francisco, CA, 94080.

4. Plaintiff Theravance Biopharma Ireland Limited is an Irish company having a registered office at Ten Earlsfort Terrace, Dublin 2, D02 T380, Ireland.

5. Plaintiff Mylan Ireland Limited is a company having a principal place of business at Newenham Court, Northern Cross, Malahide Road, Dublin 17, Ireland; and a registered office at Unit 35/36, Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland.

6. Plaintiff Mylan Specialty L.P. is a company having a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia, 26505.

7. Plaintiff Mylan Specialty L.P. sells YUPELRI® in this judicial district and throughout the United States.

8. Plaintiffs Mylan Specialty L.P. and Theravance Biopharma US, Inc. promote and market YUPELRI® in the United States.

9. Theravance Biopharma R&D IP, LLC is the assignee of the '948 patent. Theravance Biopharma R&D IP, LLC is a wholly owned subsidiary of Theravance Biopharma Ireland Limited.

10. Theravance Biopharma Ireland Limited is the exclusive licensee, and Mylan Ireland Limited is the exclusive sub-licensee, of the '948 patent. Mylan Ireland Limited is also the holder of approved New Drug Application No. 210598 for YUPELRI® (revefenacin) inhalation solution, for oral inhalation (the "YUPELRI® NDA").

Eugia

11. On information and belief, Defendant Eugia Pharma is a company organized and existing under the laws of India, with its principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad, Telangana, India, 500038.

12. On information and belief, Eugia Pharma has on some occasions identified itself as Eugia Pharma "Specialities," and on other occasions as Eugia Pharma "Specialties," including, for example, in Answers that Eugia Pharma filed in the following cases: *Pfizer Inc. et al. v. Aurobindo Pharma, Ltd. et al.*, No. 20-cv-01528, Answer (D. Del. Dec 4, 2020) ("Eugia Pharma Specialities

Ltd."); *Medicure International, Inc. v. Aurobindo Pharma Ltd. et al.*, No. 2:21-cv-17534, Answer (D.N.J. Feb. 16, 2022) ("Eugia Pharma Specialties Limited"); *Amgen Inc. et al. v. Aurobindo Pharma Ltd. et al.*, No. 22-cv-00227, Answer (D. Del. Mar 17, 2022) ("Eugia Pharma Specialties Limited"); and *Aragon Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 2-22-cv-03186, Answer (D.N.J. May 26, 2022) ("Eugia Pharma Specialities Limited").

13. On information and belief, Defendant Eugia US is a company organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

14. On information and belief, Eugia US is formerly known as AuroMedics Pharma LLC.

15. On information and belief, Defendant Aurobindo USA is a company organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

16. On information and belief, Defendant Aurobindo Ltd. is a company organized and existing under the laws of India, with its principal place of business at Plot No. 11, Survey No. 9, Water Mark Building, Kondapur, Hitech City, Hyderabad 500 084, Telangana, India.

17. On information and belief, Eugia Pharma is a wholly owned subsidiary of Aurobindo Ltd.

18. On information and belief, Eugia US is a wholly owned subsidiary of Aurobindo Ltd.

19. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd.

20. On information and belief, Eugia Pharma, Eugia US, Aurobindo USA, and Aurobindo Ltd. acted in concert to prepare and submit ANDA No. 218128 (the "Eugia ANDA")

to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Eugia ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

21. On information and belief, following any FDA approval of the Eugia ANDA, Eugia Pharma, Eugia US, Aurobindo USA, and Aurobindo Ltd. will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Eugia ANDA Product throughout the United States, including within the State of New Jersey.

Mankind

22. On information and belief, Defendant Mankind Pharma is a company organized and existing under the laws of India, with its principal place of business at 208, Okhla Industrial Estate, Phase III, New Delhi, 110020 India.

23. On information and belief, Defendant Lifestar is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 1200 MacArthur Blvd., Mahwah, New Jersey 07430.

24. On information and belief, Lifestar is a wholly owned subsidiary of Mankind Pharma.

25. On information and belief, Mankind Pharma and Lifestar acted in concert to prepare and submit ANDA No. 218089 (the "Mankind ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Mankind ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

26. On information and belief, following any FDA approval of the Mankind ANDA, Mankind Pharma and Lifestar will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Mankind ANDA Product throughout the United States, including within the State of New Jersey.

Teva

27. On information and belief, Defendant Teva Pharmaceuticals is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

28. On information and belief, Defendant Teva USA is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

29. On information and belief, Defendant Teva Industries is a company organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, Petach Tikva 49131 Israel.

30. On information and belief, Teva Pharmaceuticals is a wholly owned subsidiary of Teva Industries.

31. On information and belief, Teva USA is a wholly owned subsidiary of Teva Industries.

32. On information and belief, Teva Pharmaceuticals, Teva USA, and Teva Industries acted in concert to prepare and submit ANDA No. 217015 (the "Teva ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Teva ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

33. On information and belief, following any FDA approval of the Teva ANDA, Teva Pharmaceuticals, Teva USA, and Teva Industries will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Teva ANDA Product throughout the United States, including within the State of New Jersey.

Accord

34. On information and belief, Defendant Accord Inc. is a company organized and existing under the laws of the State of North Carolina, with its principal place of business at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703.

35. On information and belief, Defendant Accord Ltd. is a company organized and existing under the laws of India, with its principal place of business at Near Sola Bridge, Sarkhej – Gandhinagar Highway, Thaltej, Ahmedabad, Gujarat 380054, India.

36. On information and belief, Defendant Intas is a company organized and existing under the laws of India, with its principal place of business at Near Sola Bridge, Sarkhej – Gandhinagar Highway, Thaltej, Ahmedabad, Gujarat 380054, India.

37. On information and belief, Accord Inc. is a wholly owned subsidiary of Intas.

38. On information and belief, Accord Ltd. is a wholly owned subsidiary of Intas.

39. On information and belief, Accord Inc., Accord Ltd., and Intas acted in concert to prepare and submit ANDA No. 218100 (the "Accord ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Accord ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

40. On information and belief, following any FDA approval of the Accord ANDA, Accord Inc., Accord Ltd., and Intas will act in concert to commercially manufacture, import,

market, offer for sale, distribute, and/or sell the Accord ANDA Product throughout the United States, including within the State of New Jersey.

Lupin

41. On information and belief, Defendant Lupin Inc. is a company organized and existing under the laws of the State of Delaware, with a place of business at 400 Campus Drive, Somerset, New Jersey 08873.

42. On information and belief, Defendant Lupin Ltd. is a company organized and existing under the laws of India, with its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex Bandra (E), Mumbai, 400051, India.

43. On information and belief, Defendant Lupin Pharmaceuticals is a company organized and existing under the laws of Delaware, with a place of business at 400 Campus Drive, Somerset, New Jersey 08873.

44. On information and belief, Lupin Inc. is a wholly owned subsidiary of Lupin Ltd.

45. On information and belief, Lupin Pharmaceuticals is a wholly owned subsidiary of Lupin Ltd.

46. On information and belief, Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals acted in concert to prepare and submit ANDA No. 218088 (the "Lupin ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Lupin ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

47. On information and belief, following any FDA approval of the Lupin ANDA, Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals will act in concert to commercially manufacture,

import, market, offer for sale, distribute, and/or sell the Lupin ANDA Product throughout the United States, including within the State of New Jersey.

Orbicular

48. On information and belief, Defendant Orbicular is a company organized and existing under the laws of India, with its principal place of business at Plot No. 53, ALEAP Industrial Estate, Pragathi Nagar, Kukatpally, Hyderabad, 500090, India.

49. On information and belief, Orbicular prepared and submitted ANDA No. 217868 (the "Orbicular ANDA") to FDA to engage in the commercial manufacture, use, sale or offer for sale within or importation into the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Orbicular ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

50. On information and belief, following any FDA approval of the Orbicular ANDA, Orbicular will commercially manufacture, import, market, offer for sale, distribute, and/or sell the Orbicular ANDA Product throughout the United States, including within the State of New Jersey.

Cipla

51. On information and belief, Defendant Cipla Ltd. is a company organized and existing under the laws of India, with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

52. On information and belief, Defendant Cipla USA is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

53. On information and belief, Cipla USA is a wholly owned subsidiary of Cipla Ltd.

54. On information and belief, Cipla Ltd. and Cipla USA acted in concert to prepare and submit ANDA No. 217958 (the "Cipla ANDA") to FDA to engage in the commercial

manufacture, use, sale or offer for sale within or importation into, the United States, including, on information and belief, in the State of New Jersey, of a generic version of YUPELRI® (revefenacin) inhalation solution (the "Cipla ANDA Product"), for oral inhalation, prior to the expiration of the '948 patent.

55. On information and belief, following any FDA approval of the Cipla ANDA, Cipla Ltd. and Cipla USA will act in concert to commercially manufacture, import, market, offer for sale, distribute, and/or sell the Cipla ANDA Product throughout the United States, including within the State of New Jersey.

JURISDICTION AND VENUE

56. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

57. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., including 35 U.S.C. § 271.

58. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 28 U.S.C. §§ 2201 and 2202, regardless of whether the named defendants have submitted with their respective ANDAs a Paragraph IV certification to the '948 patent. *See Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1124 (Fed. Cir. 2018) ("Here, [Plaintiff's] complaint alleged that [Defendant] infringed the [] patent under 35 U.S.C. § 271(e)(2)(A) by filing the ANDA . . . Nothing more was required to establish the district court's subject matter jurisdiction pursuant to 28 U.S.C. § 1338(a).").

Eugia

59. This Court has personal jurisdiction over Eugia US at least because, on information and belief, Eugia US is a corporation with its principal place of business in the State of New Jersey, at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

60. This Court has personal jurisdiction over Aurobindo USA at least because, on information and belief, Aurobindo USA is a corporation with its principal place of business in the State of New Jersey, at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

61. This Court has personal jurisdiction over Eugia Pharma at least because, on information and belief, Eugia Pharma directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

62. This Court has personal jurisdiction over Eugia US at least because, on information and belief, Eugia US directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

63. This Court has personal jurisdiction over Aurobindo USA at least because, on information and belief, Aurobindo USA directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

64. This Court has personal jurisdiction over Aurobindo Ltd. at least because, on information and belief, Aurobindo Ltd. directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

65. This Court has personal jurisdiction over Eugia Pharma, Eugia US, Aurobindo USA, and Aurobindo Ltd. at least because, *inter alia*, on information and belief, (1) Eugia Pharma itself, and/or in concert with Eugia US, Aurobindo Ltd. and/or Aurobindo USA, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Eugia ANDA Product in the United States, including the State of New Jersey; and (2) Eugia Pharma itself, and/or in concert with Eugia US, Aurobindo Ltd. and/or Aurobindo USA, will market, distribute, offer for sale, and/or sell the Eugia ANDA Product

in the United States, including the State of New Jersey, upon approval of ANDA No. 218128, and Eugia will derive substantial revenue from the use or consumption of the Eugia ANDA Product in the State of New Jersey.

66. If Eugia Pharma's connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Eugia Pharma is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Eugia Pharma in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

67. If Aurobindo Ltd.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Aurobindo Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Aurobindo Ltd. in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

68. On information and belief, Eugia US is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration No. 5004299.

69. On information and belief, Aurobindo USA is registered as a "Wholesale" entity with the State of New Jersey's Department of Health under Registration Nos. 5003120 and 5005256.

70. On information and belief, Aurobindo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0100921223.

71. Venue is proper in this district for Eugia Pharma pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Eugia Pharma is a foreign

corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

72. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Eugia US at least because, on information and belief, Eugia US has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Eugia US has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Eugia ANDA in the State of New Jersey and/or with the intention of seeking to market the Eugia ANDA Product nationwide, including within the State of New Jersey.

73. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Aurobindo USA at least because, on information and belief, Aurobindo USA has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Aurobindo USA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Eugia ANDA in the State of New Jersey and/or with the intention of seeking to market the Eugia ANDA Product nationwide, including within the State of New Jersey.

74. Venue is proper in this district for Aurobindo Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Aurobindo Ltd. is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

75. Eugia did not contest jurisdiction and venue in a patent infringement litigation in the District of New Jersey related to the same Eugia ANDA No. 218128 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case.

See, *e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

76. On information and belief, Eugia Pharma, Aurobindo USA, and Aurobindo Ltd. have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have not contested jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See*, *e.g.*, *Eisai Co., Ltd. et al. v. Aurobindo Pharma Ltd. et al.*, No. 1-22-cv-03610 (D.N.J. June 8, 2022) (Aurobindo USA and Aurobindo Ltd.); *Aragon Pharms., Inc. et al. v. Eugia Pharma Specialities Ltd. et al.*, No. 2-22-cv-03186 (D.N.J. May 26, 2022) (Eugia Pharma and Aurobindo USA); *Medicure International, Inc. v. Aurobindo Pharma Ltd. et al.*, No. 2-21-cv-17534 (D.N.J. Sept. 24, 2021) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-21-cv-00624 (D.N.J. Jan. 12, 2021) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Merck Sharp & Dohme BV et al. v. Aurobindo Pharma USA, Inc. et al.*, No. 2-20-cv-02576 (D.N.J. Mar. 10, 2020) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-20-cv-00315 (D.N.J. Jan. 8, 2020) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, No. 2-19-cv-05799 (D.N.J. Feb. 14, 2019) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim); *Boehringer Ingelheim Pharms., Inc. et al. v. Aurobindo Pharma USA Inc. et al.*, No. 3-17-cv-07887 (D.N.J. Oct. 4, 2017) (Eugia Pharma and Aurobindo USA) (also filed a counterclaim); *Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2-17-cv-03387 (D.N.J. May 11, 2017) (Eugia Pharma, Aurobindo USA, and Aurobindo Ltd.) (also filed a counterclaim).

Mankind

77. This Court has personal jurisdiction over Lifestar at least because, on information and belief, Lifestar is a corporation with its principal place of business in New Jersey, at 1200 MacArthur Blvd, Mahwah, New Jersey 07430.

78. This Court has personal jurisdiction over Mankind Pharma at least because, on information and belief, Mankind Pharma directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

79. This Court has personal jurisdiction over Lifestar at least because, on information and belief, Lifestar directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

80. This Court has personal jurisdiction over Mankind Pharma and Lifestar at least because, *inter alia*, on information and belief, (1) Mankind Pharma itself, and/or in concert with its wholly owned subsidiary Lifestar, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Mankind ANDA Product in the United States, including the State of New Jersey; and (2) Mankind Pharma itself, and/or in concert with its wholly owned subsidiary Lifestar, will market, distribute, offer for sale, and/or sell the Mankind ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218089, and Mankind will derive substantial revenue from the use or consumption of the Mankind ANDA Product in the State of New Jersey.

81. If Mankind Pharma's connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Mankind Pharma is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Mankind Pharma in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

82. On information and belief, Lifestar is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration No. 5005074.

83. On information and belief, Lifestar is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0450064472.

84. Venue is proper in this district for Mankind Pharma pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, on information and belief, Mankind Pharma is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

85. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Lifestar at least because, on information and belief, Lifestar has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Lifestar has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Mankind ANDA in the State of New Jersey and/or with the intention of seeking to market the Mankind ANDA Product nationwide, including within the State of New Jersey.

86. Mankind did not contest jurisdiction and venue in a patent infringement litigation in the District of New Jersey related to the same Mankind ANDA No. 218089 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case. *See*, *e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

87. On information and belief, Mankind Pharma and Lifestar have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and did not contest jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See*, *e.g.*, *Bayer Intellectual Property GmbH et al. v. Mankind Pharma Ltd.*, No.

22-cv-05599 (D.N.J. Sept. 16, 2022) (Mankind Pharma); *Merck Sharp & Dohme B.V. et al. v. Mankind Pharma Ltd. et al.*, No. 2:20-cv-02787 (D.N.J. Mar. 13, 2020) (Mankind Pharma and Lifestar); *Celgene Corp. v. Mankind Pharma Ltd. et al.*, No. 3:18-cv-11081 (D.N.J. June 26, 2018) (Mankind Pharma) (also filed a counterclaim).

Teva

88. This Court has personal jurisdiction over Teva USA at least because, on information and belief, Teva USA is a corporation with its principal place of business in the State of New Jersey, at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

89. This Court has personal jurisdiction over Teva Pharmaceuticals at least because, on information and belief, Teva Pharmaceuticals is a corporation with its principal place of business in the State of New Jersey, at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

90. This Court has personal jurisdiction over Teva Pharmaceuticals at least because, on information and belief, Teva Pharmaceuticals directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

91. This Court has personal jurisdiction over Teva USA at least because, on information and belief, Teva USA directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

92. This Court has personal jurisdiction over Teva Industries at least because, on information and belief, Teva Industries directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

93. This Court has personal jurisdiction over Teva Pharmaceuticals, Teva USA, and Teva Industries at least because, *inter alia*, on information and belief, (1) Teva Pharmaceuticals itself, and/or in concert with Teva USA and/or Teva Industries, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product in the United States, including the State of New Jersey; and (2) Teva Pharmaceuticals itself, and/or in concert with Teva USA and/or Teva Industries, will market, distribute, offer for sale, and/or sell the Teva ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 217015, and Teva will derive substantial revenue from the use or consumption of the Teva ANDA Product in the State of New Jersey.

94. If Teva Industries' connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Teva Industries is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Teva Industries in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

95. On information and belief, Teva USA is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration Nos. 5000583 and 5003436.

96. On information and belief, Teva USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID. No. 0100250184.

97. On information and belief, Teva Pharmaceuticals is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0450614134.

98. Venue is proper in this district for Teva Industries pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Teva Industries is a foreign corporation organized and existing under the laws of Israel and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

99. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Teva Pharmaceuticals at least because, on information and belief, Teva Pharmaceuticals has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Teva Pharmaceuticals has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Teva ANDA in the State of New Jersey and/or with the intention of seeking to market the Teva ANDA Product nationwide, including within the State of New Jersey.

100. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Teva USA at least because, on information and belief, Teva USA has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Teva USA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Teva ANDA in the State of New Jersey and/or with the intention of seeking to market the Teva ANDA Product nationwide, including within the State of New Jersey.

101. Teva Pharmaceuticals and Teva USA did not contest jurisdiction and venue, and filed counterclaims, in a patent infringement litigation in the District of New Jersey related to the same Teva ANDA No. 217015 for approval to market the same generic version of YUPELRI®

(revefenacin) inhalation solution as in the instant case.[1] *See*, *e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

102. On information and belief, Teva Pharmaceuticals and/or Teva USA have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have consented to jurisdiction and/or venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See*, *e.g.*, *Horizon Orphan LLC, et al. v. Teva Pharms., Inc.*, No. 1-22-cv-01382 (D.N.J. Mar. 15, 2022) (Teva Pharmaceuticals); *Evoke Pharma, Inc. v. Teva Pharms., Inc., et al.*, No. 1-22-cv-02019 (Apr. 7, 2022) (Teva Pharmaceuticals and Teva USA); *Merck Sharp & Dohme BV et al. v. Teva Pharm. Indus. Ltd. et al.*, No. 2-20-cv-18972 (D.N.J. Dec. 14, 2020) (Teva USA) (also filed a counterclaim); *TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-20-cv-17496 (D.N.J. Nov. 30, 2020) (Teva USA) (also filed a counterclaim); *TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-20-cv-11087 (D.N.J. Aug. 21, 2020) (Teva USA); *TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-20-cv-08809 (D.N.J. Jul. 13, 2020) (Teva USA) (also filed a counterclaim); *TherapeuticsMD, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-20-cv-03485 (D.N.J. Apr. 1, 2020) (Teva USA) (also filed a counterclaim); *Horizon Medicines LLC v. Teva Pharms. USA, Inc.*, No. 2-20-cv-08188 (D.N.J. Jul. 2, 2020) (Teva USA) (also filed a counterclaim); *Tris Pharma, Inc. v. Teva Pharms. USA, Inc.*, No. 2-20-cv-05212 (D.N.J. Apr. 28, 2020) (Teva USA) (also filed a counterclaim); *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc. et al.*, No. 2-19-cv-21384 (D.N.J. Dec. 13, 2019) (Teva USA).

[1] Defendant Teva Industries was dismissed from that action before answering the complaint. *See Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD, D.I. 21 (D.N.J. Feb. 16, 2023).

Accord

103. This Court has personal jurisdiction over Accord Inc. at least because, on information and belief, Accord Inc. directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

104. This Court has personal jurisdiction over Accord Ltd. at least because, on information and belief, Accord Ltd. directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

105. This Court has personal jurisdiction over Intas at least because, on information and belief, Intas directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

106. This Court has personal jurisdiction over Accord Inc., Accord Ltd., and Intas at least because, *inter alia*, on information and belief, (1) Accord Inc. itself, and/or in concert with Intas and/or Accord Ltd., has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Accord ANDA Product in the United States, including the State of New Jersey; and (2) Accord Inc. itself, and/or in concert with its wholly owned subsidiaries Intas and/or Accord Ltd., will market, distribute, offer for sale, and/or sell the Accord ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218100, and Accord will derive substantial revenue from the use or consumption of the Accord ANDA Product in the State of New Jersey.

107. If Accord Ltd.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Accord Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over

Accord Ltd. in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

108. If Intas' connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Intas is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Intas in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

109. On information and belief, Intas, Accord Inc., and Accord Ltd. operate as a single integrated business. Accord Inc.'s website indicates that "Accord Healthcare, Inc., the US subsidiary of Intas Pharmaceuticals, is a leading generic pharmaceutical company . . . . Through its subsidiaries, Intas markets its products in 85 countries." *See* https://www.accordhealthcare.us/#:~:text=Accord%20Healthcare%2C%20Inc.%2C%20the,its%20products%20in%2085%20countries. (Accessed August 21, 2023).

110. Venue is proper in this district for Intas pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Intas is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

111. Venue is proper in this district for Accord Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Accord Ltd. is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

112. Accord Inc. did not contest jurisdiction and venue, and filed counterclaims, in a patent infringement litigation in the District of New Jersey related to the same Accord ANDA No. 218100 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation

solution as in the instant case.[2] *See*, *e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

113. On information and belief, Accord Inc. and Intas have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have not contested jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See*, *e.g.*, *Eagle Pharms., Inc., et al. v. Accord Healthcare Inc.*, No. 2-19-cv-09031 (D.N.J. Mar. 27, 2019) (Accord Inc.); *Sumitomo Dainippon Pharma Co., Ltd., et al. v. Aurobindo Pharma Ltd., et al.*, No. 2-18-cv-02620 (D.N.J. Feb. 23, 2018) (Accord Inc.); *Otsuka Pharms. Co., Ltd., v. Intas Pharms. Ltd., et al.*, No. 1:16-cv-05743 (D.N.J. Sept. 19, 2016) (Accord Inc. and Intas) (also filed a counterclaim); *Sanofi-Aventis US LLC v. Accord Healthcare, Inc.*, No. 3-14-cv-08079 (D.N.J. Dec. 29, 2014) (Accord Inc.) (also filed a counterclaim); *Otsuka Pharm. Co. v. Intas Pharms. Ltd., et al.*, No. 1-14-cv-03996 (D.N.J. Jun. 20, 2014) (Accord Inc. and Intas) (also filed a counterclaim).

Lupin

114. This Court has personal jurisdiction over Lupin Inc. at least because, on information and belief, Lupin Inc. is a corporation with a place of business in the State of New Jersey, at 400 Campus Drive, Somerset, New Jersey 08873.

115. This Court has personal jurisdiction over Lupin Pharmaceuticals at least because, on information and belief, Lupin Pharmaceuticals is a corporation with a place of business in the State of New Jersey, at 400 Campus Drive, Somerset, New Jersey 08873.

[2] Defendants Accord Ltd. and Intas were dismissed from that action before answering the complaint. *See Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD, D.I. 21 (D.N.J. Feb. 16, 2023).

116. This Court has personal jurisdiction over Lupin Inc. at least because, on information and belief, Lupin Inc. directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

117. This Court has personal jurisdiction over Lupin Ltd. at least because, on information and belief, Lupin Ltd. directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

118. This Court has personal jurisdiction over Lupin Pharmaceuticals at least because, on information and belief, Lupin Pharmaceuticals directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

119. This Court has personal jurisdiction over Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals at least because, *inter alia*, on information and belief, (1) Lupin Inc. itself, and/or in concert with Lupin Ltd. and/or Lupin Pharmaceuticals, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Lupin ANDA Product in the United States, including the State of New Jersey; and (2) Lupin Inc. itself, and/or in concert with Lupin Ltd. and/or Lupin Pharmaceuticals, will market, distribute, offer for sale, and/or sell the Lupin ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218088, and Lupin will derive substantial revenue from the use or consumption of the Lupin ANDA Product in the State of New Jersey.

120. If Lupin Ltd.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Lupin Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Lupin Ltd. in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

121. On information and belief, Lupin Pharmaceuticals is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration Nos. 5004060 and 5005159.

122. On information and belief, Lupin Pharmaceuticals is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID Nos. 0100953673 and 0101043376.

123. Venue is proper in this district for Lupin Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Lupin Ltd. is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

124. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Lupin Inc. at least because, on information and belief, Lupin Inc. has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Lupin Inc. has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Lupin ANDA in the State of New Jersey and/or with the intention of seeking to market the Lupin ANDA Product nationwide, including within the State of New Jersey.

125. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Lupin Pharmaceuticals at least because, on information and belief, Lupin Pharmaceuticals has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Lupin Pharmaceuticals has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Lupin ANDA

in the State of New Jersey and/or with the intention of seeking to market the Lupin ANDA Product nationwide, including within the State of New Jersey.

126. Lupin Inc. and Lupin Pharmaceuticals did not contest jurisdiction and venue, and filed counterclaims, in a patent infringement litigation in the District of New Jersey related to the same Lupin ANDA No. 218088 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case.[3] *See*, *e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

127. On information and belief, Lupin Inc., Lupin Ltd., and/or Lupin Pharmaceuticals have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and have not contested jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See*, *e.g.*, *Aragon Pharms., Inc. et al. v. Lupin Ltd. et al.*, No. 2-22-cv-02825 (D.N.J. May 13, 2022) (Lupin Ltd. and Lupin Pharmaceuticals) (also filed a counterclaim); *Jazz Pharm., Inc. v. Lupin Ltd.*, No. 2-22-cv-02773 (D.N.J. May 11, 2022) (Lupin Inc.) (also filed a counterclaim); *Bausch & Lomb, Inc. et al. v. Lupin Ltd. et al.*, No. 3-22-cv-00534 (D.N.J. Feb. 2, 2022) (Lupin Ltd.) (also filed a counterclaim); *Teva Branded Pharm. Prods. R&D, Inc. et al. v. Lupin Ltd. et al.*, No. 3-21-cv-13247 (D.N.J. Jul. 1, 2021) (Lupin Ltd.) (also filed a counterclaim); *Purple Biotech Ltd. v. Lupin Ltd. et al.*, No. 2-20-cv-12849 (D.N.J. Sept. 18, 2020) (Lupin Ltd.) (also filed a counterclaim); *Bausch Health Ireland Ltd. f/k/a Valeant Pharms. Ireland Ltd. et al. v. Lupin Ltd. et al.*, No. 1-20-cv-11039 (D.N.J. Aug. 21, 2020) (Lupin Inc.) (also filed a counterclaim); *Horizon Orphan LLC et al. v. Lupin Ltd. et al.*, No. 2-20-cv-10339 (D.N.J. Aug. 11, 2020) (Lupin Ltd. and Lupin Pharmaceuticals) (Lupin Ltd. also filed a counterclaim); *Celgene*

[3] Defendant Lupin Ltd. was dismissed from that action before answering the complaint. *See Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD, D.I. 21 (D.N.J. Feb. 16, 2023).

Corp. v. Lupin Ltd., No. 2-20-cv-08570 (D.N.J. Jul. 9, 2020) (Lupin Ltd.) (also filed a counterclaim); *Bristol-Myers Squibb Co. v. Lupin Ltd. et al.*, No. 3-20-cv-07810 (D.N.J. Jun. 25, 2020) (Lupin Inc.) (also filed a counterclaim); *Valeant Pharm. N. Am. LLC v. Lupin Ltd.*, No. 3-18-cv-13700 (Sept. 9, 2018) (Lupin Ltd.) (also filed a counterclaim).

Orbicular

128. This Court has personal jurisdiction over Orbicular at least because, on information and belief, Orbicular directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

129. This Court has personal jurisdiction over Orbicular at least because, *inter alia*, on information and belief, (1) Orbicular filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Orbicular ANDA Product in the United States, including the State of New Jersey; and (2) Orbicular will market, distribute, offer for sale, and/or sell the Orbicular ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 217868, and Orbicular will derive substantial revenue from the use or consumption of the Orbicular ANDA Product in the State of New Jersey.

130. If Orbicular's connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Orbicular is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Orbicular in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

131. Venue is proper in this district for Orbicular pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Orbicular is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

132. Orbicular did not contest jurisdiction and venue in patent infringement litigations in the District of New Jersey related to the same Orbicular ANDA No. 217868 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case. *See*, *e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Orbicular Pharmaceutical Technologies Private Ltd.*, No. 1:23-cv-02843-KMW-AMD (D.N.J. May 24, 2023); *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

133. On information and belief, Orbicular has litigated a previous Hatch-Waxman patent infringement dispute in the District of New Jersey and did not contest jurisdiction and venue in the District of New Jersey in a prior case arising out of the filing of an ANDA filing. *See Aerie Pharm., Inc. et al. v. Orbicular Pharm. Techs.*, No. 3-22-cv-01364 (D.N.J. Mar. 14, 2022).

Cipla

134. This Court has personal jurisdiction over Cipla USA at least because, on information and belief, Cipla USA is a corporation with its principal place of business in the State of New Jersey, at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059.

135. This Court has personal jurisdiction over Cipla Ltd. at least because, on information and belief, Cipla Ltd. directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

136. This Court has personal jurisdiction over Cipla USA at least because, on information and belief, Cipla USA directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

137. This Court has personal jurisdiction over Cipla Ltd. and Cipla USA at least because, *inter alia*, on information and belief, (1) Cipla Ltd. itself, and/or in concert with its wholly owned

subsidiary and agent Cipla USA, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Cipla ANDA Product in the United States, including the State of New Jersey; and (2) Cipla Ltd. itself, and/or in concert with its wholly owned subsidiary and agent Cipla USA, will market, distribute, offer for sale, and/or sell the Cipla ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 217958, and Cipla will derive substantial revenue from the use or consumption of the Cipla ANDA Product in the State of New Jersey.

138. If Cipla Ltd.'s connections with the State of New Jersey are found to be insufficient to confer personal jurisdiction, then, on information and belief, Cipla Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Cipla Ltd. in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

139. On information and belief, Cipla USA is registered as a "Manufacturer and Wholesale" entity with the State of New Jersey's Department of Health under Registration No. 5005183.

140. On information and belief, Cipla USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in the State of New Jersey under Business ID No. 0450318628.

141. Venue is proper in this district for Cipla Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, on information and belief, Cipla Ltd. is a foreign corporation organized and existing under the laws of India and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

142. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Cipla USA at least because, on information and belief, Cipla USA has a regular and established place of business in the State of New Jersey, and at least because, on information and belief, Cipla USA

has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the '948 patent that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing the Cipla ANDA in the State of New Jersey and/or with the intention of seeking to market the Cipla ANDA Product nationwide, including within the State of New Jersey.

143. Cipla did not contest jurisdiction and venue, and filed counterclaims, in a patent infringement litigation in the District of New Jersey related to the same Cipla ANDA No. 217958 for approval to market the same generic version of YUPELRI® (revefenacin) inhalation solution as in the instant case. *See*, *e.g.*, *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Limited et al.*, No. 1-23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

144. On information and belief, Cipla Ltd. and Cipla USA have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey and did not contest jurisdiction and venue in the District of New Jersey in one or more prior cases arising out of the filing of ANDAs. *See*, *e.g.*, *Par Pharm., Inc. et al. v. Cipla Ltd. et al.*, No. 2-22-cv-02814 (D.N.J. May 13, 2022) (Cipla Ltd. and Cipla USA) (also filed a counterclaim); *Teva Branded Pharm. Prods. R&D, Inc. et al. v. Cipla Ltd.*, No. 2-20-cv-14890 (D.N.J. Oct. 23, 2020) (Cipla Ltd.) (also filed a counterclaim); *Teva Branded Pharm. Prods. R&D, Inc. et al. v. Cipla Ltd.*, No. 2-20-cv-10172 (D.N.J. Aug. 7, 2020) (Cipla Ltd.) (also filed a counterclaim); *Celgene Corp. v. Cipla Ltd.*, No. 2-20-cv-07759 (D.N.J. Jun. 24, 2020) (Cipla Ltd.) (also filed a counterclaim); *Celgene Corp. v. Cipla Ltd.*, No. 2-19-cv-14731 (D.N.J. Jul. 3, 2019) (Cipla Ltd.) (also filed a counterclaim); *Cubist Pharms. LLC f/k/a Cubist Pharms., Inc. v. Cipla USA, Inc. et al.*, No. 3-19-cv-12920 (May 24, 2019) (Cipla Inc. and Cipla Ltd.) (also filed a counterclaim).

THE PATENT-IN-SUIT

145. The '948 patent, titled "Crystalline Freebase Forms of a Biphenyl Compound," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on July 4, 2023. A true and correct copy of the '948 patent is attached as Exhibit A.

146. Theravance Biopharma R&D IP, LLC is the assignee of the '948 patent. Theravance Biopharma Ireland Limited is the exclusive licensee of the '948 patent. Mylan Ireland Limited is the exclusive sub-licensee of the '948 patent from Theravance Biopharma Ireland Limited.

147. The '948 patent is listed in the Orange Book as covering YUPELRI®.

YUPELRI®

148. Plaintiffs are engaged in the business of creating, developing, and bringing to market innovative pharmaceutical products for the treatment of diseases.

149. Plaintiffs' YUPELRI® (revefenacin) is a prescription medicine indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD"), a chronic inflammatory lung disease characterized by progressive persistent airflow obstruction. Revefenacin is a long-acting muscarinic antagonist, which is often referred to as an anticholinergic. It is administered long-term as one vial of YUPELRI®, one time each day, by the orally inhaled route via a jet nebulizer.

150. FDA regulations require that approved drug products include prescribing information reciting the FDA-approved indication(s) for the drug and related instructions for healthcare providers to safely and effectively administer the drug. *See* 21 C.F.R. § 201.56(a)(1)-(3), (d)(1); 21 C.F.R. § 201.57(a)-(c).

151. Consistent with FDA regulations, the package insert for YUPELRI® includes prescribing information that recites the FDA-approved indication for YUPELRI® and provides instructions for healthcare providers and patients to safely and effectively administer YUPELRI®.

152. Attached as Exhibit B is a true and correct copy of the May 2022 YUPELRI® package insert, which is the current version of the YUPELRI® package insert.

153. YUPELRI® is indicated for the maintenance treatment of patients with COPD. (Exhibit B at § 1).

ACTS GIVING RISE TO THIS ACTION

Eugia

154. In a letter dated January 9, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Eugia Notice Letter"), Eugia notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted the Eugia ANDA to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of the Eugia ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of United States Patent Nos. 8,541,451 (the "'451 patent"), 9,765,028 (the "'028 patent"), 10,550,081 (the "'081 patent"), 11,008,289 (the "'289 patent"), and 11,484,531 (the "'531 patent").

155. Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against, *inter alia*¸ Eugia Pharma Specialities Ltd., Eugia US LLC, Aurobindo Pharma USA, Inc., and Aurobindo Pharma Limited, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

156. In a letter dated July 31, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Eugia Second Notice Letter"), Eugia notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that the Eugia ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Eugia '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Eugia ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

157. The Eugia Second Notice Letter states that "in Eugia's opinion and to the best of its knowledge, the ['948] patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Eugia's ANDA." (Eugia Second Notice Letter at 3).

158. Eugia filed the Eugia '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Eugia ANDA Product.

159. Eugia also attached to the Eugia Second Notice Letter a "Detailed Factual and Legal Basis for Eugia's Paragraph IV Certification Regarding [the '948 patent]."

160. The Eugia Second Notice Letter does not provide a substantive unenforceability defense to the '948 patent in the "Detailed Factual and Legal Basis."

161. Eugia's filing of its ANDA No. 218128 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

162. On information and belief, the active ingredient of the Eugia ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

163. On information and belief, Eugia asserts in ANDA No. 218128 that the Eugia ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Eugia, demonstrate the bioequivalence of the Eugia ANDA Product to YUPELRI®.

164. On information and belief, Eugia is seeking approval to market the Eugia ANDA Product for the same approved indication as YUPELRI®.

165. On information and belief, Eugia is seeking approval to market the Eugia ANDA Product for maintenance treatment of patients with COPD.

166. On information and belief, Eugia had knowledge of the '948 patent when it submitted and filed the Eugia '948 Patent Paragraph IV Certification to ANDA No. 218128.

167. On information and belief, Eugia intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 218128 and prior to the expiration of the '948 patent.

168. On information and belief, Eugia will commercially manufacture, use, offer for sale, and/or sell the Eugia ANDA Product throughout the United States, and/or import the Eugia ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the '948 patent.

169. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Eugia with respect to infringement of the '948 patent.

170. This action is being commenced within 45 days of receipt of the Eugia Second Notice Letter.

Mankind

171. In a letter dated January 5, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Mankind Notice Letter"), Mankind notified Mylan Ireland Limited and Theravance Biopharma US, Inc. that it had submitted the Mankind ANDA to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of the Mankind ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent.

172. Plaintiffs filed a complaint for infringement of the '451 patent, '028 patent, '081 patent, '289 patent, and '531 patent against, *inter alia*, Mankind Pharma and Lifestar, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

173. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

174. In a letter dated July 10, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Mankind Second Notice Letter"), Mankind notified Mylan Ireland Limited and Theravance Biopharma US, Inc. that the Mankind ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Mankind '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Mankind ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

175. The Mankind Second Notice Letter states that "in its opinion, the '948 patent is invalid and/or not infringed by" the Mankind ANDA Product. (Mankind Second Notice Letter at 2).

176. Mankind filed the Mankind '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Mankind ANDA Product.

177. Mankind also attached to the Mankind Second Notice Letter a "Detailed Statement of the Factual and Legal Basis for its Opinion that U.S. Patent No. 11,691,948 is invalid, unenforceable and/or will not be infringed by Mankind's manufacture, use, offer for sale, or sale of Mankind's Revefenacin inhalation solution vials (175 mcg / 3 mL)."

178. The Mankind Second Notice Letter does not provide a substantive unenforceability defense to the '948 patent in the "Detailed Statement."

179. Mankind's filing of its ANDA No. 218089 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

180. On information and belief, the active ingredient of the Mankind ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

181. On information and belief, Mankind asserts in ANDA No. 218089 that the Mankind ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Mankind, demonstrate the bioequivalence of the Mankind ANDA Product to YUPELRI®.

182. On information and belief, Mankind is seeking approval to market the Mankind ANDA Product for the same approved indication as YUPELRI®.

183. On information and belief, Mankind is seeking approval to market the Mankind ANDA Product for maintenance treatment of patients with COPD.

184. On information and belief, Mankind had knowledge of the '948 patent when it submitted and filed the Mankind '948 Patent Paragraph IV Certification to ANDA No. 218089.

185. On information and belief, Mankind intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 218089 and prior to the expiration of the '948 patent.

186. On information and belief, Mankind will commercially manufacture, use, offer for sale, and/or sell the Mankind ANDA Product throughout the United States, and/or import the Mankind ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the '948 patent.

187. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Mankind with respect to infringement of the '948 patent.

188. This action is being commenced within 45 days of receipt of the Mankind Second Notice Letter.

Teva

189. In a letter dated January 5, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Teva Notice Letter"), Teva notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 217015 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed revefenacin inhalation solution, for oral inhalation (the

"Teva ANDA Product"), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent.

190. Plaintiffs filed a complaint for infringement of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent against, *inter alia*, Teva Pharmaceuticals, Teva USA, and Teva Industries, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

191. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

192. Teva's filing of its ANDA No. 217015 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

193. On information and belief, the active ingredient of the Teva ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

194. On information and belief, Teva asserts in ANDA No. 217015 that the Teva ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Teva, demonstrate the bioequivalence of the Teva ANDA Product to YUPELRI®.

195. On information and belief, Teva is seeking approval to market the Teva ANDA Product for the same approved indication as YUPELRI®.

196. On information and belief, Teva is seeking approval to market the Teva ANDA Product for maintenance treatment of patients with COPD.

197. On information and belief, Teva has knowledge of the '948 patent.

198. On information and belief, Teva intends to and will infringe one or more claims of the ’948 patent upon receiving FDA approval of ANDA No. 217015 and prior to the expiration of the ’948 patent.

199. On information and belief, Teva will commercially manufacture, use, offer for sale, and/or sell the Teva ANDA Product throughout the United States, and/or import the Teva ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the ’948 patent.

200. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Teva with respect to infringement of the ’948 patent.

Accord

201. In a letter dated January 6, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the “Accord Notice Letter”), Accord notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted the Accord ANDA to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of the Accord ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the ’451 patent, the ’028 patent, the ’081 patent, the ’289 patent, and the ’531 patent.

202. Plaintiffs filed a complaint for infringement of the ’451 patent, the ’028 patent, the ’081 patent, the ’289 patent, and the ’531 patent against, *inter alia*, Accord Inc., Accord Ltd., and Intas, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

203. On July 4, 2023, the ’948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

204. In a letter dated July 19, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Accord Second Notice Letter"), Accord notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that the Accord ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Accord '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Accord ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

205. Accord's filing of its ANDA No. 218100 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

206. The Accord Second Notice Letter states that, in its opinion, the '948 patent is "invalid, unenforceable, and/or will not be infringed" by the Accord ANDA Product. (Accord Second Notice Letter at 1.)

207. Accord filed the Accord '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Accord ANDA Product.

208. Accord also attached a "detailed statement of the factual and legal basis of Accord's opinion that U.S. Patent No. 11691948 is invalid, unenforceable, and/or will not be infringed."

209. The Accord Second Notice Letter does not provide a substantive invalidity and unenforceability defense to the '948 patent in the "Detailed Statement."

210. On information and belief, the active ingredient of the Accord ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

211. On information and belief, Accord asserts in ANDA No. 218100 that the Accord ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Accord, demonstrate the bioequivalence of the Accord ANDA Product to YUPELRI®.

212. On information and belief, Accord is seeking approval to market the Accord ANDA Product for the same approved indication as YUPELRI®.

213. On information and belief, Accord is seeking approval to market the Accord ANDA Product for maintenance treatment of patients with COPD.

214. On information and belief, Accord had knowledge of the '948 patent when it submitted and filed the Accord '948 Patent Paragraph IV Certification to ANDA No. 218100.

215. On information and belief, Accord intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 218100 and prior to the expiration of the '948 patent.

216. On information and belief, Accord will commercially manufacture, use, offer for sale, and/or sell the Accord ANDA Product throughout the United States, and/or import the Accord ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the '948 patent.

217. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Accord with respect to infringement of the '948 patent. This action is being commenced within 45 days of receipt of the Accord Second Notice Letter.

Lupin

218. In a letter dated January 5, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Lupin Notice Letter"), Lupin notified Mylan Ireland

Limited and Theravance Biopharma R&D IP LLC that it had submitted ANDA No. 218088 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed revefenacin inhalation solution, for oral inhalation (the "Lupin ANDA Product"), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent.

219. Plaintiffs filed a complaint for infringement of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent against, *inter alia*, Lupin Inc., Lupin Ltd., Lupin Pharmaceuticals, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

220. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

221. In a letter dated August 3, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Lupin Second Notice Letter"), Lupin notified Mylan Ireland Limited, Mylan Pharmaceuticals Inc., Theravance Biopharma R&D IP LLC, and Theravance Biopharma Ireland Ltd. that the Lupin ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Lupin '948 Patent Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use, or sale of the Lupin ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '948 patent.

222. The Lupin Second Notice Letter states that "in its opinion and to the best of its knowledge, each claim of the '948 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Lupin's ANDA" (Lupin Second Notice Letter at 2).

223. Lupin filed the Lupin '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Lupin ANDA Product.

224. Lupin also attached to the Lupin Second Notice Letter a "Detailed Statement of the Factual and Legal Bases for Lupin 's ANDA Certification That the Claims of U.S. Patent No. 11,691,948 Will Not Be Infringed, Are Invalid, and/or Are Unenforceable."

225. The Lupin Second Notice Letter does not provide a substantive unenforceability defense to the '948 patent in the "Detailed Statement."

226. Lupin's filing of its ANDA No. 218088 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

227. On information and belief, the active ingredient of the Lupin ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

228. On information and belief, Lupin asserts in ANDA No. 218088 that the Lupin ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Lupin, demonstrate the bioequivalence of the Lupin ANDA Product to YUPELRI®.

229. On information and belief, Lupin is seeking approval to market the Lupin ANDA Product for the same approved indication as YUPELRI®.

230. On information and belief, Lupin is seeking approval to market the Lupin ANDA Product for maintenance treatment of patients with COPD.

231. On information and belief, Lupin had knowledge of the '948 patent when it submitted and filed the Lupin '948 Patent Paragraph IV Certification to ANDA No. 218088.

232. On information and belief, Lupin intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 218088 and prior to the expiration of the '948 patent.

233. On information and belief, Lupin will commercially manufacture, use, offer for sale, and/or sell the Lupin ANDA Product throughout the United States, and/or import the Lupin ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the '948 patent.

234. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Lupin with respect to infringement of the '948 patent.

235. This action is being commenced within 45 days of receipt of the Lupin Second Notice Letter.

Orbicular

236. In a letter dated January 13, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Orbicular Notice Letter"), Orbicular notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 217868 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed revefenacin inhalation solution, for oral inhalation (the "Orbicular ANDA Product"), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, and the '289 patent.

237. Plaintiffs filed a complaint for infringement of the ’451 patent, the ’028 patent, the ’081 patent, and the ’289 patent against, *inter alia*¸ Orbicular, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

238. In a letter dated April 12, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the “Orbicular Second Notice Letter”), Orbicular notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had amended the Orbicular ANDA to contain a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use, or sale of the Orbicular ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the ’531 patent.

239. Plaintiffs filed a complaint for infringement of the ’531 patent against Orbicular in this jurisdiction on May 24, 2023, which was assigned Civil Action No. 23-02843-KMW-AMD, and later consolidated into 23-00926-KMW-AMD.

240. On July 4, 2023, the ’948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

241. In a letter dated August 10, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the “Orbicular Third Notice Letter”), Orbicular notified Mylan Ireland Limited, Viatris Inc., and Theravance Biopharma R&D IP, LLC that the Orbicular ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the “Orbicular ’948 Patent Paragraph IV Certification”) to obtain approval to engage in the commercial manufacture, use, or sale of the Orbicular ANDA Product, as a generic version of YUPELRI® in/into the United States, prior to the expiration of the ’948 patent.

242. The Orbicular Third Notice Letter states that the '948 patent "is invalid, unenforceable, and/or will not be infringed by" the Orbicular ANDA Product. (Orbicular Third Notice Letter at 2).

243. Orbicular filed the Orbicular '948 Patent Paragraph IV Certification without adequate justification for asserting that the '948 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Orbicular ANDA Product.

244. Orbicular also attached to the Orbicular Third Notice Letter a "Detailed Statement of the Factual and Legal Bases for Orbicular's Assertion of Invalidity, Unenforceability, and/or Noninfringement of U.S. Patent No. 11,691,948 Regarding Revefenacin Inhalation Solution, 175 mcg/3 mL."

245. The Orbicular Third Notice Letter does not provide a substantive invalidity and/or unenforceability defense to the '948 patent in the "Detailed Statement."

246. Orbicular's filing of its ANDA No. 217868 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

247. On information and belief, the active ingredient of the Orbicular ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

248. On information and belief, Orbicular asserts in ANDA No. 217868 that the Orbicular ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Orbicular, demonstrate the bioequivalence of the Orbicular ANDA Product to YUPELRI®.

249. On information and belief, Orbicular is seeking approval to market the Orbicular ANDA Product for the same approved indication as YUPELRI®.

250. On information and belief, Orbicular is seeking approval to market the Orbicular ANDA Product for maintenance treatment of patients with COPD.

251. On information and belief, Orbicular had knowledge of the '948 patent when it submitted and filed the Orbicular '948 Patent Paragraph IV Certification to ANDA No. 217868.

252. On information and belief, Orbicular intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 217868 and prior to the expiration of the '948 patent.

253. On information and belief, Orbicular will commercially manufacture, use, offer for sale, and/or sell the Orbicular ANDA Product throughout the United States, and/or import the Orbicular ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the '948 patent.

254. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Orbicular with respect to infringement of the '948 patent.

255. This action is being commenced within 45 days of receipt of the Orbicular Third Notice Letter.

Cipla

256. In a letter dated January 17, 2023, purporting to be notice under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "Cipla Notice Letter"), Cipla notified Mylan Ireland Limited and Theravance Biopharma R&D IP, LLC that it had submitted ANDA No. 217958 to the FDA under Section 21 U.S.C. §§ 355(j)(1) and 2(A), seeking approval to engage in the commercial manufacture, use, or sale of its proposed revefenacin inhalation solution, for oral inhalation (the

"Cipla ANDA Product"), as a generic version of YUPELRI® in/into the United States, prior to the expiration of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent.

257. Plaintiffs filed a complaint for infringement of the '451 patent, the '028 patent, the '081 patent, the '289 patent, and the '531 patent against, *inter alia*, Cipla Ltd. and Cipla USA, in this jurisdiction on February 16, 2023, which was assigned Civil Action No. 23-00926-KMW-AMD.

258. On July 4, 2023, the '948 patent was granted and thereafter included in the Orange Book on July 5, 2023, in connection with the Orange Book listing for YUPELRI®.

259. Cipla's filing of its ANDA No. 217958 constitutes infringement of the '948 patent under at least 35 U.S.C. § 271(e)(2)(A).

260. On information and belief, the active ingredient of the Cipla ANDA Product is revefenacin, which is the same active ingredient in YUPELRI® and the same active ingredient used in the compositions described and claimed in one or more claims of the '948 patent.

261. On information and belief, Cipla asserts in ANDA No. 217958 that the Cipla ANDA Product is bioequivalent to YUPELRI®, refers to and relies upon the YUPELRI® NDA, and contains data that, according to Cipla, demonstrate the bioequivalence of the Cipla ANDA Product to YUPELRI®.

262. On information and belief, Cipla is seeking approval to market the Cipla ANDA Product for the same approved indication as YUPELRI®.

263. On information and belief, Cipla is seeking approval to market the Cipla ANDA Product for maintenance treatment of patients with COPD.

264. On information and belief, Cipla has knowledge of the '948 patent.

265. On information and belief, Cipla intends to and will infringe one or more claims of the '948 patent upon receiving FDA approval of ANDA No. 217958 and prior to the expiration of the '948 patent.

266. On information and belief, Cipla will commercially manufacture, use, offer for sale, and/or sell the Cipla ANDA Product throughout the United States, and/or import the Cipla ANDA Product into the United States, promptly upon receiving FDA approval to do so and during the term of the '948 patent.

267. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Plaintiffs and Cipla with respect to infringement of the '948 patent.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY EUGIA

268. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

269. Eugia's submission of ANDA No. 218128 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Eugia ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

270. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

271. Eugia's commercial manufacture, sale, offer for sale, or use of the Eugia ANDA Product within the United States, or importation of the Eugia ANDA Product into the United

States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

272. On information and belief, Eugia intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Eugia ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218128 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

273. On information and belief, Eugia had knowledge of the '948 patent when it submitted the Eugia '948 Patent Paragraph IV Certification as part of ANDA No. 218128. Eugia's infringement has been, and continues to be, deliberate.

274. Plaintiffs will be substantially and irreparably harmed if Eugia's infringement of the '948 patent is not enjoined.

275. Plaintiffs do not have an adequate remedy at law.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY MANKIND

276. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

277. Mankind's submission of ANDA No. 218089 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Mankind ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

278. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the

United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

279. Mankind's commercial manufacture, sale, offer for sale, or use of the Mankind ANDA Product within the United States, or importation of the Mankind ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

280. On information and belief, Mankind intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mankind ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218089 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

281. On information and belief, Mankind had knowledge of the '948 patent when it submitted the Mankind '948 Patent Paragraph IV Certification as part of ANDA No. 218089. Mankind's infringement has been, and continues to be, deliberate.

282. Plaintiffs will be substantially and irreparably harmed if Mankind's infringement of the '948 patent is not enjoined.

283. Plaintiffs do not have an adequate remedy at law.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY TEVA

284. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

285. Teva's submission of ANDA No. 217015 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Teva ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes

infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

286. Teva's commercial manufacture, sale, offer for sale, or use of the Teva ANDA Product within the United States, or importation of the Teva ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

287. Teva's commercial manufacture, sale, offer for sale, or use of the Teva ANDA Product within the United States, or importation of the Teva ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

288. On information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Teva ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217015 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

289. On information and belief, Teva has knowledge of the '948 patent. Teva's infringement has been, and continues to be, deliberate.

290. Plaintiffs will be substantially and irreparably harmed if Teva's infringement of the '948 patent is not enjoined.

291. Plaintiffs do not have an adequate remedy at law.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY ACCORD

292. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

293. Accord's submission of ANDA No. 218100 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Accord ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

294. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

295. Accord's commercial manufacture, sale, offer for sale, or use of the Accord ANDA Product within the United States, or importation of the Accord ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

296. On information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Accord ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218100 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

297. On information and belief, Accord had knowledge of the '948 patent when it submitted the Accord '948 Patent Paragraph IV Certification as part of ANDA No. 218100. Accord's infringement has been, and continues to be, deliberate.

298. Plaintiffs will be substantially and irreparably harmed if Accord's infringement of the '948 patent is not enjoined.

299. Plaintiffs do not have an adequate remedy at law.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY LUPIN

300. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

301. Lupin's submission of ANDA No. 218088 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Lupin ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

302. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

303. Lupin's commercial manufacture, sale, offer for sale, or use of the Lupin ANDA Product within the United States, or importation of the Lupin ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

304. On information and belief, Lupin intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Lupin ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 218088 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

305. On information and belief, Lupin had knowledge of the '948 patent when it submitted the Lupin '948 Patent Paragraph IV Certification as part of ANDA No. 218088. Lupin's infringement has been, and continues to be, deliberate.

306. Plaintiffs will be substantially and irreparably harmed if Lupin's infringement of the '948 patent is not enjoined.

307. Plaintiffs do not have an adequate remedy at law.

COUNT VI
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY ORBICULAR

308. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

309. Orbicular's submission of ANDA No. 217868 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Orbicular ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

310. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

311. Orbicular's commercial manufacture, sale, offer for sale, or use of the Orbicular ANDA Product within the United States, or importation of the Orbicular ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

312. On information and belief, Orbicular intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Orbicular ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217868 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

313. On information and belief, Orbicular had knowledge of the '948 patent when it submitted the Orbicular '948 Patent Paragraph IV Certification as part of ANDA No. 217868. Orbicular's infringement has been, and continues to be, deliberate.

314. Plaintiffs will be substantially and irreparably harmed if Orbicular's infringement of the '948 patent is not enjoined.

315. Plaintiffs do not have an adequate remedy at law.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 11,691,948 BY CIPLA

316. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

317. Cipla's submission of ANDA No. 217958 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of the Cipla ANDA Product in/into the United States prior to the expiration of the '948 patent constitutes infringement, either literally or under the doctrine of equivalents, of one or more claims of the '948 patent under 35 U.S.C. § 271(e)(2)(A).

318. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

319. Cipla's commercial manufacture, sale, offer for sale, or use of the Cipla ANDA Product within the United States, or importation of the Cipla ANDA Product into the United States, during the term of the '948 patent would infringe one or more claims of the '948 patent under 35 U.S.C. § 271(g).

320. On information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Cipla ANDA Product, and the proposed labeling therefor, immediately and imminently upon the approval of ANDA No. 217958 and any amendments thereto, *i.e.*, prior to the expiration of the '948 patent.

321. On information and belief, Cipla has knowledge of the '948 patent. Cipla's infringement has been, and continues to be, deliberate.

322. Plaintiffs will be substantially and irreparably harmed if Cipla's infringement of the '948 patent is not enjoined.

323. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

Eugia

(a) A judgment that Eugia under 35 U.S.C. § 271(e)(2)(A) has infringed one or more claims of the '948 patent by the filing of its amended ANDA No. 218128;

(b) A judgment that Eugia's manufacturing, using, selling, offering for sale, and/or importing the Eugia ANDA Product in/into the United States will infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a) and/or (g);

(c) A declaration under 28 U.S.C. §§ 2201-02 that if Eugia, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the Eugia ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a) and/or (g);

(d) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 218128 under Section 505(j) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '948 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(e) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Eugia, whether alone or in concert with a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of the Eugia ANDA Product before the expiration of the '948 patent, inclusive of any extension(s) to patent term;

(f) A permanent injunction restraining and enjoining Eugia, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing the Eugia ANDA Product or any pharmaceutical composition as claimed in the '948 patent in/into the United States, or practicing any processes or methods as claimed in the '948 patent, or from actively inducing or contributing to the infringement of any claim of the '948 patent, before the expiration of the '948 patent, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(g) Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, and damages under 35 U.S.C. § 271(e)(4)(C), to Plaintiffs if Eugia engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Eugia ANDA Product prior to the latest expiration date of the '948 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(h) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(i) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);

(j) Costs and expenses in this action; and

(k) Such further and other relief as this Court may deem just and proper.

Mankind

(l) A judgment that Mankind under 35 U.S.C. § 271(e)(2)(A) has infringed one or more claims of the '948 patent by the filing of its ANDA No. 218089;

(m) A judgment that Mankind's manufacturing, using, selling, offering for sale, and/or importing the Mankind ANDA Product in/into the United States will infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a) and/or (g);

(n) A declaration under 28 U.S.C. §§ 2201-02 that if Mankind, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the Mankind ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a) and/or (g);

(o) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 218089 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '948 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(p) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Mankind, whether alone or in concert with a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of the Mankind ANDA Product before the expiration of the '948 patent, inclusive of any extension(s) to patent term;

(q) A permanent injunction restraining and enjoining Mankind, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing the Mankind ANDA Product or any pharmaceutical composition as claimed in the '948 patent in/into the United States, or practicing any processes or methods as claimed in the '948 patent, or

from actively inducing or contributing to the infringement of any claim of the '948 patent, before the expiration of the '948 patent, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(r) Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, and damages under 35 U.S.C. § 271(e)(4)(C), to Plaintiffs if Mankind engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Mankind ANDA Product prior to the latest expiration date of the '948 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(s) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(t) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);

(u) Costs and expenses in this action; and

(v) Such further and other relief as this Court may deem just and proper.

Teva

(w) A judgment that Teva under 35 U.S.C. § 271(e)(2)(A) has infringed one or more claims of the '948 patent by the filing of its ANDA No. 217015;

(x) A judgment that Teva's manufacturing, using, selling, offering for sale, and/or importing the Teva ANDA Product in/into the United States will infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a) and/or (g);

(y) A declaration under 28 U.S.C. §§ 2201-02 that if Teva, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the Teva ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a) and/or (g);

(z) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 217015 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '948 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(aa) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Teva, whether alone or in concert with a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of the Teva ANDA Product before the expiration of the '948 patent, inclusive of any extension(s) to patent term;

(bb) A permanent injunction restraining and enjoining Teva, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing the Teva ANDA Product or any pharmaceutical composition as claimed in the '948 patent in/into the United States, or practicing any processes or methods as claimed in the '948 patent, or from actively inducing or contributing to the infringement of any claim of the '948 patent, before the expiration of the '948 patent, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(cc) Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, and damages under 35 U.S.C. § 271(e)(4)(C), to Plaintiffs if Teva engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Teva ANDA Product prior to the latest expiration date of the '948 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(dd) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(ee) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);

(ff) Costs and expenses in this action; and

(gg) Such further and other relief as this Court may deem just and proper.

Accord

(hh) A judgment that Accord under 35 U.S.C. § 271(e)(2)(A) has infringed one or more claims of the '948 patent by the filing of its ANDA No. 218100;

(ii) A judgment that Accord's manufacturing, using, selling, offering for sale, and/or importing the Accord ANDA Product in/into the United States will infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a) and/or (g);

(jj) A declaration under 28 U.S.C. §§ 2201-02 that if Accord, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the Accord ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a) and/or (g);

(kk) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 218100 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '948 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(ll) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Accord, whether alone or in concert with a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of the Accord ANDA Product before the expiration of the '948 patent, inclusive of any extension(s) to patent term;

(mm) A permanent injunction restraining and enjoining Accord, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing

the Accord ANDA Product or any pharmaceutical composition as claimed in the '948 patent in/into the United States, or practicing any processes or methods as claimed in the '948 patent, or from actively inducing or contributing to the infringement of any claim of the '948 patent, before the expiration of the '948 patent, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(nn) Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, and damages under 35 U.S.C. § 271(e)(4)(C), to Plaintiffs if Accord engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Accord ANDA Product prior to the latest expiration date of the '948 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(oo) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(pp) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);

(qq) Costs and expenses in this action; and

(rr) Such further and other relief as this Court may deem just and proper.

Lupin

(ss) A judgment that Lupin under 35 U.S.C. § 271(e)(2)(A) has infringed one or more claims of the '948 patent by the filing of its ANDA No. 218088;

(tt) A judgment that Lupin's manufacturing, using, selling, offering for sale, and/or importing the Lupin ANDA Product in/into the United States will infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a) and/or (g);

(uu) A declaration under 28 U.S.C. §§ 2201-02 that if Lupin, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation

of the Lupin ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a) and/or (g);

(vv) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 218088 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '948 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(ww) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Lupin, whether alone or in concert with a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of the Lupin ANDA Product before the expiration of the '948 patent, inclusive of any extension(s) to patent term;

(xx) A permanent injunction restraining and enjoining Lupin, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing the Lupin ANDA Product or any pharmaceutical composition as claimed in the '948 patent in/into the United States, or practicing any processes or methods as claimed in the '948 patent, or from actively inducing or contributing to the infringement of any claim of the '948 patent, before the expiration of the '948 patent, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(yy) Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, and damages under 35 U.S.C. § 271(e)(4)(C), to Plaintiffs if Lupin engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Lupin ANDA Product prior to the latest expiration date of the '948 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(zz) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(aaa) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);

(bbb) Costs and expenses in this action; and

(ccc) Such further and other relief as this Court may deem just and proper.

Orbicular

(ddd) A judgment that Orbicular under 35 U.S.C. § 271(e)(2)(A) has infringed one or more claims of the '948 patent by the filing of its ANDA No. 217868;

(eee) A judgment that Orbicular's manufacturing, using, selling, offering for sale, and/or importing the Orbicular ANDA Product in/into the United States will infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a) and/or (g);

(fff) A declaration under 28 U.S.C. §§ 2201-02 that if Orbicular, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the Orbicular ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a) and/or (g);

(ggg) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 217868 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '948 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(hhh) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Orbicular, whether alone or in concert with a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the

United States of the Orbicular ANDA Product before the expiration of the '948 patent, inclusive of any extension(s) to patent term;

(iii) A permanent injunction restraining and enjoining Orbicular, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing the Orbicular ANDA Product or any pharmaceutical composition as claimed in the '948 patent in/into the United States, or practicing any processes or methods as claimed in the '948 patent, or from actively inducing or contributing to the infringement of any claim of the '948 patent, before the expiration of the '948 patent, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(jjj) Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, and damages under 35 U.S.C. § 271(e)(4)(C), to Plaintiffs if Orbicular engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Orbicular ANDA Product prior to the latest expiration date of the '948 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(kkk) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(lll) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);

(mmm) Costs and expenses in this action; and

(nnn) Such further and other relief as this Court may deem just and proper.

Cipla

(ooo) A judgment that Cipla under 35 U.S.C. § 271(e)(2)(A) has infringed one or more claims of the '948 patent by the filing of its ANDA No. 217958;

(ppp) A judgment that Cipla's manufacturing, using, selling, offering for sale, and/or importing the Cipla ANDA Product in/into the United States will infringe one or more claims of the '948 patent under 35 U.S.C. § 271(a) and/or (g);

(qqq) A declaration under 28 U.S.C. §§ 2201-02 that if Cipla, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the Cipla ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a) and/or (g);

(rrr) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 217958 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date not earlier than the latest expiration date of the '948 patent, inclusive of any extension(s) or additional period(s) of exclusivity;

(sss) A judgment under 35 U.S.C. §§ 271(e)(4)(B) and 283 providing injunctive relief against Cipla, whether alone or in concert with a subsidiary company, to prevent the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of the Cipla ANDA Product before the expiration of the '948 patent, inclusive of any extension(s) to patent term;

(ttt) A permanent injunction restraining and enjoining Cipla, whether alone or in concert with a subsidiary company, from making, using, selling, offering for sale, and/or importing the Cipla ANDA Product or any pharmaceutical composition as claimed in the '948 patent in/into the United States, or practicing any processes or methods as claimed in the '948 patent, or from actively inducing or contributing to the infringement of any claim of the '948 patent, before the expiration of the '948 patent, inclusive of any extension(s) to patent term in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(uuu) Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, and damages under 35 U.S.C. § 271(e)(4)(C), to Plaintiffs if Cipla engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Cipla ANDA Product prior to the latest expiration date of the '948 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

(vvv) To the extent the facts show that this is an exceptional case, an award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(www) An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4);

(xxx) Costs and expenses in this action; and

(yyy) Such further and other relief as this Court may deem just and proper.

Dated: August 21, 2023

Respectfully submitted,

/s/ Arnold B. Calmann
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel hereby certifies that this matter in controversy is the subject of the following litigation, pending in this District: *Theravance Biopharma R&D IP, LLC et al. v. Eugia Pharma Specialities Ltd. et al.*, Consolidated Case No. 1:23-cv-00926-KMW-AMD (D.N.J. Feb. 16, 2023).

Dated: August 21, 2023

Respectfully submitted,

/s/ Arnold B. Calmann

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LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel hereby certifies that the Complaint seeks injunctive and other equitable relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: August 21, 2023

Respectfully submitted,

/s/ Arnold B. Calmann

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